

114TH CONGRESS
2D SESSION

S. 2700

To update the authorizing provisions relating to the workforces of the National Institutes of Health and the Food and Drug Administration, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 17, 2016

Mr. ALEXANDER (for himself and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To update the authorizing provisions relating to the workforces of the National Institutes of Health and the Food and Drug Administration, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*

2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA and NIH Work-

5 force Authorities Modernization Act”.

1 **SEC. 2. SILVIO O. CONTE SENIOR BIOMEDICAL RESEARCH**2 **SERVICE.**

3 (a) HIRING AND RETENTION AUTHORITY.—Section
4 228 of the Public Health Service Act (42 U.S.C. 237) is
5 amended—

6 (1) in the section heading, by inserting “AND
7 BIOMEDICAL PRODUCT ASSESSMENT” after “RE-
8 SEARCH”;

9 (2) in subsection (a)—

10 (A) in paragraph (1), by striking “Silvio
11 O. Conte Senior Biomedical Research Service,
12 not to exceed 500 members” and inserting
13 “Silvio O. Conte Senior Biomedical Research
14 and Biomedical Product Assessment Service (in
15 this section referred to as the ‘Service’), not to
16 exceed 2,000 members, the purpose of which is
17 to recruit and retain outstanding and qualified
18 scientific and technical experts in the fields of
19 biomedical research, clinical research evalua-
20 tion, and biomedical product assessment”;

21 (B) by amending paragraph (2) to read as
22 follows:

23 “(2) The authority established in paragraph (1) may
24 not be construed to require the Secretary to reduce the
25 number of employees serving under any other employment

1 system in order to offset the number of members serving
2 in the Service.”; and

3 (C) by adding at the end the following:

4 “(3) The Secretary shall assign experts under this
5 section to agencies within the Department of Health and
6 Human Services taking into account the need for the ex-
7 pertise of such expert.”;

8 (3) in subsection (b)—

9 (A) in the matter preceding paragraph (1),
10 by striking “or clinical research evaluation” and
11 inserting “, clinical research evaluation, or bio-
12 medical product assessment”; and

13 (B) in paragraph (1), by inserting “or a
14 doctoral or master’s level degree in engineering,
15 bioinformatics, or a related or emerging field,”
16 after the comma;

17 (4) in subsection (d)(2), by striking “and shall
18 not exceed the rate payable for level I of the Execu-
19 tive Schedule unless approved by the President
20 under section 5377(d)(2) of title 5, United States
21 Code” and inserting “and shall not exceed the
22 amount of annual compensation (excluding expenses)
23 specified in section 102 of title 3, United States
24 Code’;

25 (5) by striking subsection (e); and

1 (6) by redesignating subsections (f) and (g) as
2 subsections (e) and (f), respectively.

3 (b) GAO STUDY.—

4 (1) IN GENERAL.—The Comptroller General of
5 the United States shall conduct a study of the effec-
6 tiveness of the amendments to section 228 of the
7 Public Health Service Act (42 U.S.C. 237) made by
8 subsection (a) and the impact of such amendments,
9 if any, on all agencies or departments of the Depart-
10 ment of Health and Human Services, and, not later
11 than 4 years after the date of enactment of this Act,
12 shall submit a report based on such study to the
13 Committee on Health, Education, Labor, and Pen-
14 sions of the Senate and the Committee on Energy
15 and Commerce of the House of Representatives.

16 (2) CONTENT OF STUDY AND REPORT.—The
17 study and report under paragraph (1) shall include
18 an examination of the extent to which recruitment
19 and retention of outstanding and qualified scientific,
20 medical, or technical experts in the fields of bio-
21 medical research, clinical research evaluation, and
22 biomedical product assessment has improved or oth-
23 erwise has been affected by the amendments to sec-
24 tion 228 of the Public Health Service Act (42
25 U.S.C. 237) made by subsection (a), including by

1 determining, during the period between the date of
2 enactment of this Act and the completion of the
3 study—

4 (A) the total number of members recruited
5 and retained under the Senior Biomedical Re-
6 search and Biomedical Product Assessment
7 Service under such section 228, and the effect
8 of increasing the number of members eligible
9 for such Service;

10 (B) the number of members of such Senior
11 Biomedical Research and Biomedical Product
12 Assessment Service hired with a doctoral level
13 degree in biomedicine or a related field, or doc-
14 toral or master's level degree in engineering,
15 bioinformatics, or a related or emerging field;
16 and

17 (C) how many Senior Biomedical Research
18 and Biomedical Product Assessment Service
19 members have been hired by each agency or de-
20 partment of the Department of Health and
21 Human Services, and how such Department as-
22 signs such members to each agency or depart-
23 ment.

**1 SEC. 3. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL,
2 AND PROFESSIONAL PERSONNEL.**

3 (a) IN GENERAL.—The Federal Food, Drug, and
4 Cosmetic Act is amended by inserting after section 714
5 (21 U.S.C. 379d–3) the following:

**6 "SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECH-
7 NICAL, AND PROFESSIONAL PERSONNEL.**

8 "(a) IN GENERAL.—The Secretary may, without re-
9 gard to the provisions of title 5, United States Code, gov-
10 erning appointments in the competitive service, appoint
11 outstanding and qualified candidates to scientific, tech-
12 nical, or professional positions that support the develop-
13 ment, review, and regulation of medical products. Such po-
14 sitions shall be within the competitive service.

15 "(b) COMPENSATION.—

16 “(1) IN GENERAL.—Notwithstanding any other
17 provision of law, including any requirement with re-
18 spect to General Schedule pay rates under sub-
19 chapter III of chapter 53 of title 5, United States
20 Code, and consistent with the requirements of para-
21 graph (2), the Commissioner of Food and Drugs
22 may determine and fix—

“(A) the annual rate of pay of any individual appointed under subsection (a); and

25 “(B) for purposes of retaining qualified
26 employees, the annual rate of pay for any quali-

1 fied scientific, technical, or professional per-
2 sonnel appointed to a position described in sub-
3 section (a) before the date of enactment of this
4 section.

5 “(2) LIMITATION.—The annual rate of pay es-
6 tablished pursuant to paragraph (1) may not exceed
7 the amount of annual compensation (excluding ex-
8 penses) specified in section 102 of title 3, United
9 States Code.

10 “(3) PUBLIC AVAILABILITY.—The annual rate
11 of pay provided to an individual in accordance with
12 this section shall be publicly available information.

13 “(c) RULE OF CONSTRUCTION.—The authorities
14 under this section shall not be construed to affect the au-
15 thority provided under section 714.

16 “(d) REPORT ON WORKFORCE PLANNING.—

17 “(1) IN GENERAL.—Not later than 18 months
18 after the date of enactment of the FDA and NIH
19 Workforce Authorities Modernization Act, the Sec-
20 retary shall submit a report on workforce planning
21 to the Committee on Health, Education, Labor, and
22 Pensions of the Senate and the Committee on En-
23 ergy and Commerce of the House of Representatives
24 that examines the extent to which the Food and
25 Drug Administration has a critical need for qualified

1 individuals for scientific, technical, or professional
2 positions, including—

3 “(A) an analysis of the workforce needs at
4 the Food and Drug Administration and the
5 Secretary’s strategic plan for addressing such
6 needs, including through use of the authority
7 under this section; and

8 “(B) a recruitment and retention plan for
9 hiring qualified scientific, technical, and profes-
10 sional candidates, which may include the use
11 of—

12 “(i) recruitment through non-govern-
13 mental recruitment or placement agencies;

14 “(ii) recruitment through academic in-
15 stitutions;

16 “(iii) recruitment or hiring bonuses, if
17 applicable;

18 “(iv) recruitment using targeted direct
19 hiring authorities; and

20 “(v) retention of qualified scientific,
21 technical, and professional employees using
22 the authority under this section, or other
23 applicable authorities of the Secretary.

24 “(2) RECOMMENDATIONS.—The report under
25 paragraph (1) may include the recommendations of

1 the Commissioner of Food and Drugs that would
2 help the Food and Drug Administration to better re-
3 cruit and retain qualified individuals for scientific,
4 technical, or professional positions at the agency.”.

5 (b) GAO STUDY AND REPORT.—

6 (1) IN GENERAL.—The Comptroller General of
7 the United States shall conduct a study of the abil-
8 ity of the Food and Drug Administration to hire,
9 train, and retain qualified scientific, technical, and
10 professional staff, not including contractors, nec-
11 essary to fulfill the mission of the Food and Drug
12 Administration to protect and promote public health.
13 Not later than January 1, 2022, the Comptroller
14 General shall submit a report on such study to the
15 Committee on Health, Education, Labor, and Pen-
16 sions of the Senate and the Committee on Energy
17 and Commerce of the House of Representatives.

18 (2) CONTENTS OF STUDY.—The Comptroller
19 General shall include in the study and report under
20 paragraph (1)—

21 (A) information about the progress of the
22 Food and Drug Administration in recruiting
23 and retaining qualified scientific, technical, and
24 professional staff outstanding in the field of

1 biomedical research, clinical research evalua-
2 tion, and biomedical product assessment;

3 (B) the extent to which critical staffing
4 needs exist at the Food and Drug Administra-
5 tion, and barriers to hiring, training, and re-
6 taining qualified staff, if any;

7 (C) an examination of the recruitment and
8 retention strategies of the Food and Drug Ad-
9 ministration, including examining any strategic
10 workforce plan, focused on improving scientific,
11 technical, and professional staff recruitment
12 and retention; and

13 (D) recommendations for potential im-
14 provements that would address staffing needs
15 of the Food and Drug Administration.

16 **SEC. 4. ESTABLISHMENT OF FOOD AND DRUG ADMINISTRA-**
17 **TION INTERCENTER INSTITUTES.**

18 (a) IN GENERAL.—Chapter X of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
20 ed by adding at the end the following:

21 **“SEC. 1014. FOOD AND DRUG ADMINISTRATION INTER-**
22 **CENTER INSTITUTES.**

23 “(a) IN GENERAL.—The Secretary shall establish one
24 or more Intercenter Institutes within the Food and Drug
25 Administration (referred to in this section as an ‘Insti-

1 tute') for a major disease area or areas. With respect to
2 the major disease area of focus of an Institute, such Insti-
3 tute shall develop and implement processes for coordina-
4 tion of activities, as applicable to such major disease area
5 or areas, between the Center for Drug Evaluation and Re-
6 search, the Center for Biologics Evaluation and Research,
7 and the Center for Devices and Radiological Health (for
8 the purposes of this section, referred to as the 'Centers').

9 Such activities may include—

10 “(1) coordination of staff from the Centers with
11 diverse product expertise in the diagnosis, cure, miti-
12 gation, treatment, or prevention of the specific dis-
13 eases relevant to the major disease area of focus of
14 the Institute;

15 “(2) streamlining, where appropriate, the re-
16 view of medical products to diagnose, cure, mitigate,
17 treat, or prevent the major disease area of focus of
18 the Institute, applying relevant standards under sec-
19 tions 505, 510(k), and 515 of this Act and section
20 351 of the Public Health Service Act, and other ap-
21 plicable authorities;

22 “(3) promotion of scientific programs within
23 the Centers related to the major disease area of
24 focus of the Institute;

1 “(4) development of programs and enhancement
2 of strategies to recruit, train, and provide continuing
3 education opportunities for the personnel of the Cen-
4 ters with expertise related to the major disease area
5 of focus of the Institute;

6 “(5) enhancement of the interactions of the
7 Centers with patients, sponsors, and the external
8 biomedical community regarding the major disease
9 area of focus of the Institute; and

10 “(6) facilitation of the collaborative relation-
11 ships of the Centers with other agencies within the
12 Department of Health and Human Services regard-
13 ing the major disease area of focus of the Institute.

14 “(b) IMPLEMENTATION PLAN.—Prior to establishing
15 an Institute under subsection (a), and not later than 1
16 year after the date of enactment of the FDA and NIH
17 Workforce Authorities Modernization Act, the Secretary
18 shall publish a draft implementation plan for such Insti-
19 tute, and provide for not less than 60 calendar days for
20 public comment on such plan.

21 “(c) TIMING.—The Secretary shall establish at least
22 one Institute under subsection (a) within 1 year of the
23 closing of the public comment period under subsection (b),
24 unless the Secretary determines that establishing such In-
25 stitute would not be feasible or would not benefit the pub-

1 lic health, and publishes such determination on the public
2 Internet website of the Food and Drug Administration.

3 “(d) TERMINATION OF INSTITUTES.—The Secretary
4 may terminate any Institute established pursuant to this
5 section if the Secretary determines such Institute is no
6 longer benefitting the public health. Not less than 60 days
7 prior to so terminating an Institute, the Secretary shall
8 provide public notice, including the rationale for such ter-
9 mination.”.

10 (b) TECHNICAL AMENDMENTS.—Chapter X of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391
12 et seq.) is amended—

13 (1) by redesignating section 1012 as section
14 1013; and

15 (2) by redesignating the second section 1011
16 (with respect to improving the training of State,
17 local, territorial, and tribal food safety officials), as
18 added by section 209(a) of the FDA Food Safety
19 Modernization Act (Public Law 111–353), as section
20 1012.

21 **SEC. 5. SCIENTIFIC MEETINGS.**

22 (a) IN GENERAL.—Scientific meetings that are at-
23 tended by scientific or medical personnel, or other profes-
24 sionals, of the Department of Health and Human Services
25 for whom attendance at such meeting is directly related

1 to their professional duties and the mission of the Depart-
2 ment—

3 (1) shall not be considered conferences for the
4 purposes of complying with Federal reporting re-
5 quirements contained in annual appropriations Acts
6 or in this section; and

7 (2) shall not be considered conferences for pur-
8 poses of a restriction contained in an annual appro-
9 priations Act, based on Office of Management and
10 Budget Memorandum M-12-12 or any other regula-
11 tion restricting such travel.

12 (b) LIMITATION.—Nothing in this section shall be
13 construed to exempt travel for scientific meetings from
14 Federal regulations relating to travel.

15 (c) REPORTS.—Each operating division of the De-
16 partment of Health and Human Services shall prepare,
17 and post on an Internet website of the operating division,
18 an annual report on scientific meeting attendance and re-
19 lated travel spending for each fiscal year. Such report shall
20 include—

21 (1) general information concerning the scientific
22 meeting activities involved;
23 (2) information concerning the total amount ex-
24 pended for such meetings;

1 (3) a description of all such meetings that were
2 attended by scientific or medical personnel, or other
3 professionals, of each such operating division where
4 the total amount expended by the operating division
5 associated with each such meeting are in excess of
6 \$30,000, including—

- 7 (A) the total amount of meeting expenses
8 incurred by the operating division for such
9 meeting;
- 10 (B) the location of such meeting;
- 11 (C) the date of such meeting;
- 12 (D) a brief explanation on how such meet-
13 ing advanced the mission of the operating divi-
14 sion; and
- 15 (E) the total number of individuals whose
16 travel expenses or other scientific meeting ex-
17 penses were paid by the operating division; and
- 18 (4) with respect to any such meeting where the
19 total expenses to the operating division exceeded
20 \$150,000, a description of the exceptional cir-
21 cumstances that necessitated the expenditure of such
22 amounts.

23 **SEC. 6. REAGAN-UDALL FOUNDATION FOR THE FOOD AND**
24 **DRUG ADMINISTRATION.**

25 (a) BOARD OF DIRECTORS.—

1 (1) COMPOSITION AND SIZE.—Section
2 770(d)(1)(C) of the Federal Food, Drug, and Cos-
3 metic Act (21 U.S.C. 379dd(d)(1)(C)) is amended—
4 (A) by redesignating clause (ii) as clause
5 (iii);
6 (B) by inserting after clause (i) the fol-
7 lowing:

8 “(ii) ADDITIONAL MEMBERS.—The
9 Board, through amendments to the bylaws
10 of the Foundation, may provide that the
11 number of voting members of the Board
12 shall be a number (to be specified in such
13 amendment) greater than 14. Any Board
14 positions that are established by any such
15 amendment shall be appointed (by majority
16 vote) by the individuals who, as of the date
17 of such amendment, are voting members of
18 the Board and persons so appointed may
19 represent any of the categories specified in
20 subclauses (I) through (V) of clause (i), so
21 long as no more than 30 percent of the
22 total voting members of the Board (includ-
23 ing members whose positions are estab-
24 lished by such amendment) are representa-
25 tives of the general pharmaceutical, device,

1 food, cosmetic, and biotechnology indus-
2 tries.”; and

3 (C) in clause (iii)(I), as redesignated by
4 subparagraph (A), by striking “The ex officio
5 members shall ensure” and inserting “The ex
6 officio members, acting pursuant to clause (i),
7 and the Board, acting pursuant to clause (ii),
8 shall ensure”.

9 (2) FEDERAL EMPLOYEES ALLOWED TO SERVE
10 ON BOARD.—Clause (iii)(II) of section 770(d)(1)(C)
11 of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 379dd(d)(1)(C)), as redesignated by para-
13 graph (1)(A), is amended by adding at the end the
14 following: “For purposes of this section, the term
15 ‘employee of the Federal Government’ does not in-
16 clude a ‘special Government employee’, as that term
17 is defined in section 202(a) of title 18, United
18 States Code.”.

19 (3) STAGGERED TERMS.—Subparagraph (A) of
20 section 770(d)(3) of the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 379dd(d)(3)) is amended
22 to read as follows:

23 “(A) TERM.—The term of office of each
24 member of the Board appointed under para-
25 graph (1)(C)(i), and the term of office of any

1 member of the Board whose position is estab-
2 lished pursuant to paragraph (1)(C)(ii), shall be
3 4 years, except that—

4 “(i) the terms of offices for the mem-
5 bers of the Board initially appointed under
6 paragraph (1)(C)(i) shall expire on a stag-
7 gered basis as determined by the ex officio
8 members; and

9 “(ii) the terms of office for the per-
10 sons initially appointed to positions estab-
11 lished pursuant to paragraph (1)(C)(ii)
12 may be made to expire on a staggered
13 basis, as determined by the individuals
14 who, as of the date of the amendment es-
15 tablishing such positions, are members of
16 the Board.”.

17 (b) EXECUTIVE DIRECTOR COMPENSATION.—Section
18 770(g)(2) of the Federal Food, Drug, and Cosmetic Act
19 (21 U.S.C. 379dd(g)(2)) is amended by striking “but shall
20 not be greater than the compensation of the Commis-
21 sioner”.

22 (c) SEPARATION OF FUNDS.—Section 770(m) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379dd(m)) is amended by striking “are held in separate
25 accounts from funds received from entities under sub-

1 section (i)” and inserting “are managed as individual pro-
2 grammatic funds under subsection (i), according to best
3 accounting practices”.

4 **SEC. 7. NIH RESEARCH INFORMATION COLLECTION EX-**
5 **EMPTED FROM PAPERWORK REDUCTION**
6 **ACT.**

7 Section 301 of the Public Health Service Act (42
8 U.S.C. 241) is amended by adding to the end the fol-
9 lowing:

10 “(f) PAPERWORK REDUCTION.—Subchapter I of
11 chapter 35 of title 44, United States Code, shall not apply
12 to the collection of information during the conduct of re-
13 search by the National Institutes of Health.”.

14 **SEC. 8. STUDIES.**

15 The Federal Food, Drug, and Cosmetic Act is amend-
16 ed—

17 (1) in section 505(k)(5) (21 U.S.C.
18 355(k)(5))—

19 (A) in subparagraph (A), by inserting
20 “and” after the semicolon;

21 (B) by striking subparagraph (B); and

22 (C) by redesignating subparagraph (C) as
23 subparagraph (B);

24 (2) in section 505A (21 U.S.C. 355a), by strik-
25 ing subsection (p);

- 1 (3) in section 505B (21 U.S.C. 355c)—
2 (A) by striking subsection (l); and
3 (B) by redesignating subsection (m) as
4 subsection (l); and
5 (4) in section 523 (21 U.S.C. 360m), by strik-
6 ing subsection (d).

○